28.2.23

READY

Qualitative Data Analysis Plan

Contents

1. Administrative Information

FULL/LONG TITLE OF THE STUDY A Realist Evaluation of Paramedics Working in General Practice: Work Package 2: An assessment of clinical and cost effectiveness (READY Paramedics)

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1.6 Roles and responsibility

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2. Introduction

2.1 Study Background and Rationale

General Practices are under sustained pressure due to increasing demand for healthcare, and an aging population [Hobbs 2016; Baird 2016]. The number of General Practitioners (GPs) is falling as recruitment and retention to GP posts has not increased in line with workload demand. GP services are increasingly turning to other staff to address medical workforce shortages, including paramedics [NHS England GPFV, 2016]. However, paramedics have variable skills, experience, training and models of employment and as yet the full scale of their contribution to the delivery of general practice services is not known.

The READY study is a realist evaluation to assess the clinical and cost-effectiveness of paramedics working in general practice and make recommendations about service implementation across a range of contexts.

2.2 Aims and Objectives

The aims of the study are to evaluate the role of paramedics in GP services and to provide evidence about different service delivery models to determine their ability to:

Achieve good clinical outcomes for patients.

Improve patient experience.

Relieve GP workload pressure.

Influence the workload of other general practice staff.

Make efficient use of healthcare resources.

In addition to the above, the study aims to examine the potential unintended consequences of deploying Paramedics in General Practices (PGP).

The objectives of the study will be addressed either qualitatively, quantitatively or with mixed methods in two phases as follows:

WP1: Rapid realist review and consensus exercise

A rapid realist review has been conducted to synthesise currently available information, explore the domains of variation in existing models of service delivery, and produce a set of realist initial programme theories about how different models work with which resources in

different situations. The initial programme theories were validated and refined through a series of consensus exercises involving a broad range of stakeholders.

WP2: Realist evaluation and case studies

A realist evaluation, including case studies (general practices), to test the programme theories in England by applying quantitative and qualitative methods. Qualitative interview data will be collected from patients, carers, and health professionals to understand the barriers and facilitators to PGP and the impact it has on access to general practice. Further to this, data will be collected to analyse the implications of different models of PGP compared to no PGP on healthcare resource utilisation, costs and patient-reported outcomes and safety outcomes to assess clinical and cost-effectiveness of different models. This will combine prospective data (questionnaires) and retrospective data (routine data extracts from primary health care records).

2.3 Realist Evaluation

Realist evaluation is a theory-driven approach to understanding complex interventions in complex environments. It draws on both constructivist (theory building) and positivist (theory testing) paradigms to offer causal explanations about generative forces that underpin intended and unintended outcomes in a process termed retroduction. Realist evaluation seeks to understand what works, for whom, in what circumstances, how and why. The approach is methodologically robust and systematic and facilitates a clear understanding of the interactions between context and mechanisms that influence the outcomes of interventions [Pawson 2013; Westhorp 2011]. Realist evaluation has been adopted for this study due to the variation in the provision of paramedics in general practices, and the need to explain how key components (e.g. types of patients seen or modality of consultations) may work in a variety of ways in different contexts (practice socio-demographics).

Qualitative study data is particularly important in a realist evaluation as retroductive processes require detailed understanding of the underlying forces or mechanisms that determine the behaviour of individuals or groups in response to an intervention. These mechanisms are often not visible or clearly articulated, but can be uncovered through discussion and interviews, probing for deeper drivers of personal or social behaviour [Jagosh 2020]. Whilst it may be possible to use quantitative data to explore contexts, outcomes and the associations between them, qualitative data can illuminate the underpinning mechanisms that may not otherwise be apparent. Rather that purely documenting the interviewee's views or lived experience, the focus of data collection is the development, refinement and testing of theories that can explain how and why a certain mechanism is triggered (or not) in a given context, and how that leads to the observed outcomes of an intervention [Marchal 2018]. Used together, qualitative and quantitative data can help to explain how and in what

circumstances an intervention works most effectively, leading to guidance to support the successful development and implementation of complex interventions [Pawson & Tilley 1997].

2.4. Research Questions

- How does PGP care impact on patient clinical outcomes (e.g. unplanned hospital admissions, repeat service uses, prescriptions, referrals, tests and investigations)?

  Addressed using quantitative routine data and qualitative data (e.g. perceptions from staff about increases in referrals, or prescriptions etc)

- How does PGP care impact on patient reported outcomes (e.g. concern, confidence in health plan, ability to manage symptoms, health related quality of life) compared to non-PGP care?

  Addressed from questionnaires + interview data

- Does PGP result in patient reported safe management?

  Addressed from questionnaires + interview data

- What are the direct costs/savings associated with PGP care and does it provide good value for money?

  Health economics evaluation, based on routine primary care data extracts and patient questionnaire data

- Does PGP lead to improved patient experience; how and for which patients?

  Realist interview data + questionnaires + quantitative comparative analysis

- How and why does PGP affect the workload of GPs and other general practice staff?

  Realist interview data + quantitative data

3. Study Design

3.1 Study Design

The programme theories developed in WP1 will be tested using a series of case studies with 34 sites (general practices) across England. 25 sites will have paramedics who work with general practices, and 9 will be control sites, with no paramedic service to their patients.

Qualitative data will derive from 11/25 paramedic sites and 4/9 control sites, where patients and staff will be invited for interviews. In addition, study participant patients will be asked to fill in questionnaires with free text responses to questions about the safe delivery of care from their local practices, and areas for improvement.

All sites will contribute quantitative questionnaire data – see separate data analysis plan (DAP) for further details.

3.2 Qualitative Analytic Framework

Interviews will consider three main levels of exploration for theory development that pertain to the introduction of paramedics into general practice:

Micro level: focussing on the individuals involved

Meso level: focussing on the day-to-day practice activity to deliver services to patients

Macro level: the practice-wide systems, structures and policies required to support the provision of general practice services by paramedics in primary care

Building on WP1 theories, data collection and analysis will focus on developing theories about the following:

- Role acceptability – what works, for whom? At the level of the individual (patients, GPs, paramedics, other practice staff, practice managers)

  understanding of the role,

  acceptability of the role,

  satisfaction with how it is working, or not

- Providing a service - General practice in action on a day-to-day basis:

  Referral to paramedic services: who decides who sees a patient? Does this system work well for patients/staff?

Range of paramedic services: acute presentations, home visits, telephone triage, special interests, prescribing: what works, for whom, and why?

- Supporting a sustainable service: management/structural aspects of having a paramedic service in general practice

  Funding and employment models: implications of funding and employment directly by practice, by PCN, ARRS funding, rotational provision within ambulance workforce. - what works, for whom, and why?

  Staff support and training models:

  Induction programmes for paramedics – models of these, what works for whom and why?

  Supervision during ongoing practice – What works, for whom and why?

  Integration and teamwork – what works, for whom, how and why? Models of peer support, physical location/office space, other ways?

Wider issues for exploration (this list may evolve with emergent qualitative findings):

- Impact beyond general practices – eg service delivery more widely

  Recruitment and retention of ambulance staff?

  Models for career development?

  Recruitment and retention of GPs?

  Risk management in primary care

  PGPs – taking on new decision-making responsibilities

  GPs – sharing responsibility across team members

  Impact on indemnity, complaints management etc

  Negotiating new boundaries

  Continuity of care vs benefits of rapid access?

  Holistic or generalist care vs problem-based focus?

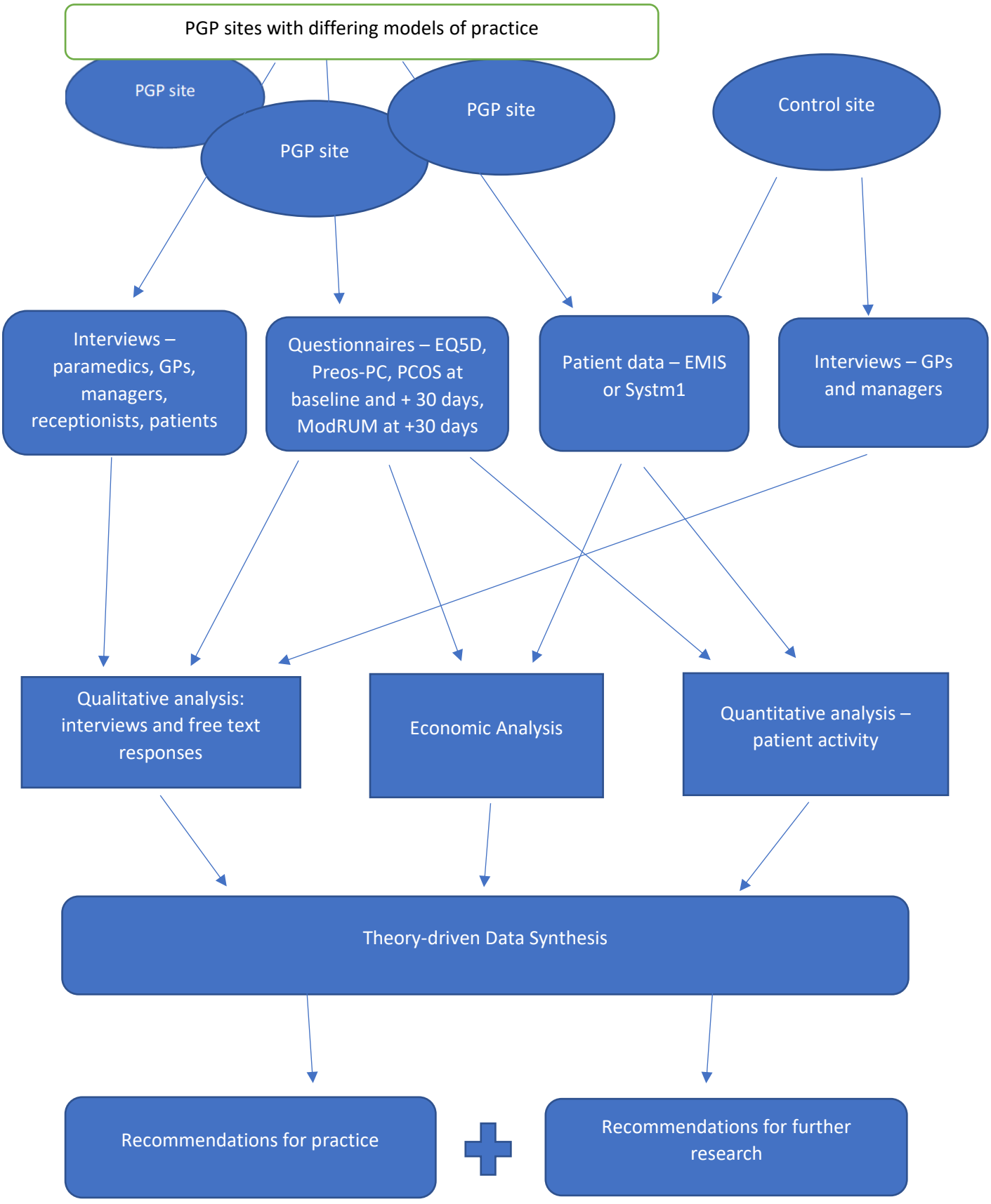
  Teamwork vs autonomous practice?

  Adapting to change – how to do this most effectively?

> Consider the future of general practice, acute care management, chronic care management, workload drift from secondary to primary care, etc. How will models be able to adapt to potential future changes?

Theories may be initially described using If-Then-Because statements, but as data is explored the focus will include explaining the relationships between contexts, mechanisms and outcomes in order to identify and test the various elements of programme theory as data collection proceeds. Theory development will be supported by clear links to evidence (such as sample quotes), and areas where evidence has not been found and are based on abductive theorising will be identified as such (marked as “hunches”). Theories will be presented as explanatory statements with a CMOC framework, and linked to relevant middle range theories as appropriate.

Framework for Data Integration in READY



3.3 Mixed Methods Analytic Framework

Building on theory development in WP1, the findings in WP2 will be brought together as a convergent synthesis based on results. This will be an iterative process, aiming to create new knowledge and gain new insights that would not be possible with a single evidence type [Astbury 2018]. For instance, findings from qualitative interviews may support interpretation of quantitative results. Quantitative information and statistical generalisations may support the validation of theories or themes generated by qualitative evidence. Juxtaposition of qualitative and quantitative data may lead to insights to examine mechanisms of action, and knowledge about contexts may lead to understandings about the relevance of findings and their transferability to other settings.

The process of combining results obtained through mixed methods will depend on close working arrangements between all analytic teams, shared understanding of key variables and why they matter, and regular joint review to support an iterative process, alongside key stakeholders. As such, it is difficult to be prescriptive at an early stage about the exact nature of the analysis plan, but it will be conducted in line with RAMESES quality standards [Greenhalgh, 2017; Wong 2017].

4. Study Population and data collection

Eligible participants include adults (16 years or older) with capacity to consent, who receive an appointment in a general practice service with either a GP (at control sites) or a Paramedic (at PGP sites) during the study data collection period. All consulting modalities (electronic, video, telephone, face-to-face in clinic, home visits) are eligible. All participants will complete two questionnaires, one at the time of their initial appointment, and one 30 days later. These questionnaires include the following measurement instruments: EQ5D-5L, the PCOQ, the PREOS-PC Compact, the MODRUM. The majority of this data will be used in the quantitative and health economic analysis, but free-text fields in the PREOS-PC compact will be analysed qualitatively. All participants completing questionnaires will be invited to opt-in to interview, and in the event of overrecruiting these interviews will be purposively sampled to achieve demographic variation and spread across the working framework of PGP models. Practices will display posters to invite potential participants to interview alone (without questionnaire completion) if they prefer. Additionally, the study will draw an interview sample from clinical and administrative staff at PGP and control sites, to understand the perspectives of those organising and delivering services at an operational level.

5 Analysis

5.1 Realist coding and analysis methods – interview data

A total of approximately 70 interviews is anticipated. Interviewees will include paramedics working in general practice, GPs, other clinical staff (e.g. Advanced Nurse Practitioners), non-clinical staff (managers or receptionists) and patients from practices with a paramedic, and from GPs and managers from "control" practices where there is no paramedic. Interviews will follow agreed semi-structured interview guides, focussing on the elicitation of perceived outcomes, and descriptions of contexts and hypothecated mechanisms. This exploratory process be inductive, leading to the development of new theories (theory-gleaning) or may present opportunities for the interviewer to present proposed theories to the interviewee for confirmation or refinement (theory testing). The content of the interviews will evolve over time in line with theory development and will vary to incorporate knowledge about how any relevant contextual factors may trigger, or inhibit, mechanisms and thus account for variable outcomes. All interviews will be audio recorded.

After the interviews, the interviewer will record reflections on the interview on the site "pen portrait" summary which contains basic demographic information about the site and participants, generated when the site was recruited to the study.

5.1.1. Data storage, transcription

Audio recordings will be given an anonymised reference code and stored on the main project file, and sent for transcription via secure electronic transfer for verbatim recording. Anonymised transcripts will be stored on the main project file with access limited to members of the READY team.

5.1.2 Coding processes

Interview analysis involves three components: direct, indirect and holistic coding. Holistic coding will be undertaken by any members of the data collection team as they familiarise themselves with interview content, in order to capture broad themes/new insights/eureka moments, or general responses to the interview content and tone. These will be documented on copies of the word document using comments, and kept in the "Team Analysis" file.

Indirect coding will involve a more focussed, theory-driven assessment of interview content, looking for evidence to confirm, refute or refine existing theories, or generate new theories.

Direct coding will be undertaken by one researcher, bringing together interview content, annotations on the transcripts, reflective notes from interviews and key information from site

pen portraits. These will be brought together as a site summary document, to collate particular theories that evolve from interviews at a particular site.

5.1.3 Computer-assisted qualitative data analysis software (CADQAS)

Anonymised interviews and site summaries will be uploaded onto NVivo software for direct coding and documentation of theories across multiple sites [Gilmour 2019]. Case characteristics generated for each site will allow cross-site and cross-model comparison for key postulated contextual features such as site location (urban/rural/mixed), the embeddedness of a paramedic service or level of practice of the paramedic. Other site characteristics may evolve as the study provides a greater understanding of key contextual variables to account for outcomes. The use of NVivo will also allow comparison of responses across different respondent groups (e.g. paramedics vs GPs vs patients vs managers).

NVivo will provide a convenient method for the storage of qualitative data that transparently links data extracts to theory development, through the use of memo documentation, linked word documents, and reflective notes [Dalkin 2020]. Access to NVivo files will be limited to a few members of the qualitative analysis team.

5.2 Survey responses

5.2.1 Coding and analysis of free text responses

A total return of 1000+ questionnaires is expected, including initial and 30-day follow up responses from patients. Most of these will be analysed using quantitative methods, but some include free text. Responses to Questions 7 & 8 on PREOS PC (specifically, “what does your surgery do well to make sure that healthcare is provided safely?”, and “what changes would you suggest they make to ensure that it is provided safely?”) will be collated on Excel.

The free text elements of the survey data will be used to test, counter or nuance emerging wider theories about patient safety and role-acceptability across the PGP models that are developed from the interview data. Informed by the principles of corpus linguistics, an initial word frequency table will support the rapid identification of recurring topics in the data, which will be mapped onto theory areas already identified through interview analysis. These will be analysed using a bespoke framework to compare paramedic vs control practice responses, baseline and follow-up changes, or other divisions as may become relevant as the theory development process proceeds. In addition, scrutiny of longer passages of free text responses, the use of textual emphasis (capital letters, exclamation marks or underlining), or

detailed clinical examples will support identification of key detail to be added to site summaries for coding and analysis using NVivo.

5.3 Quality assurance

5.3.1 Transparency

When amalgamating data from an array of data sources to generate theories, transparency is key to the credibility of findings [Wong 2017]. Transparency will be assured through shared access to original data sources and shared access to coded data (via direct, indirect or holistic coding). Theory development from interview data can be tracked with connections to supporting evidence using the site summaries. Twenty percent of transcripts will be second-coded, looking for congruence of meaning as the unit of interest, and any discrepancies in meaning discussed with the qualitative analysis team.

5.3.2 Discussion and consensus

Provisional theory concepts will be presented and discussed with other members of the READY team on a regular basis, with monthly team meetings and ad-hoc discussion as needed. Input from the wider READY study team, including those involved with analysis of economic and quantitative data, will guide the synthesis of mixed-methods data, and decision-making about key areas of interest.

5.3.3 Stakeholder input

The PPI group will review provisional theory development at intervals as it progresses, to ensure that findings are relevant and meaningful for patients.

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